DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Re: Aptivus
Docket No.: 2006E-0033

SEP 6 2006

The Honorable Jon Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Box Patent Extension
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent No. 5,852,195, filed by Pharmacia & Upjohn Company, LLC, under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Aptivus (tipranavir), the human drug product claimed by the patent.

The total length of the regulatory review period for Aptivus (tipranavir) is 3,114 days. Of this time, 2,931 days occurred during the testing phase and 183 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: December 14, 1996.

   The applicant claims December 13, 1996, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was December 14, 1996, which was thirty days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: December 22, 2004.

   The applicant claims December 21, 2004, as the date the new drug application (NDA) for Aptivus (NDA 21-814) was initially submitted. However, FDA records indicate that NDA 21-814 was submitted as a complete marketing application on December 22, 2004.

3. The date the application was approved: June 22, 2005.

   FDA has verified the applicant's claim that NDA 21-814 was approved on June 22, 2005.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Alan Stempel
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